Patent Application Number: 10/077,972

Attached to this Response is a clean sheet of each of the corrected pages of the specification incorporating the above-presented amendments and a marked-up copy of the amended claim.

In the event the Examiner considers personal contact advantageous to the disposition of this case, the Examiner is hereby authorized to call Applicants' attorney, Duane C. Basch, at Telephone Number (585) 387-0280, East Rochester, New York.

Respectfully submitted,

Duane C. Basch

Attorney for Applicant

Registration No. 34,545

Greenwald & Basch LLP

349 West Commercial Street – Suite 2490

East Rochester, New York 14445-2408

(585) 387-0280

DCB/dcb/mjn

Patent Application Number: 10/077,972 Attorney Docket Number: BTI-6

where the electrodes contact the heart. A further result of this ablation and scarring is that the sensitive node that the electrode is intended to pace with low voltage signals becomes desensitized, so that pacing the patient's heart becomes less reliable, and in some cases fails altogether.

OCT 1 1 2002 1

5

10

15

20

25

Another conventional solution for protecting the implantable medical device from electromagnetic interference is illustrated in Figure 1. Figure 1 is a schematic view of an implantable medical device 12 embodying protection against electrical interference. At least one lead 14 is connected to the implantable medical device 12 in connector block region 13 using an interface.

In the case where implantable medical device 12 is a pacemaker implanted in a body 10, the pacemaker 12 includes at least one or both of pacing and sensing leads represented generally as leads 14 to sense electrical signals attendant to the depolarization and repolarization of the heart 16, and to provide pacing pulses for causing depolarization of cardiac tissue in the vicinity of the distal ends thereof.

Figure 2 more particularly illustrates the circuit that is used conventionally to protect from electromagnetic interference. As shown in Figure 2, protection circuitry 15 is provided using a diode array component 30. The diode array consists of five zener diode triggered semiconductor controlled rectifiers (SCRs) with anti-parallel diodes arranged in an array with one common connection. This allows for a small footprint despite the large currents that may be carried through the device during defibrillation, e.g., 10 amps. The SCRs 20-24 turn on and limit the voltage across the device when excessive voltage and current surges occur.

As shown in Figure 2, each of the zener diode triggered SCRs 20-24 is connected to an electrically conductive pin 25, 26, 28 & 29. Further, each electrically conductive pin 25, 26, 28 & 29 is connected to a medical device contact region 31, 32, 34 & 35 to be wire bonded to pads of a printed circuit board. The diode array component 30 is connected to the electrically conductive pins 25, 26, 28 & 29 via the die contact regions along with other electrical conductive traces of the printed circuit board.

5

10

15

20

25

Other attempts have been made to protect implantable devices from MRI fields. For example, United States Patent 5,968,083 (to Ciciarelli et al.) describes a device adapted to switch between low and high impedance modes of operation in response to EMI insult. Furthermore, United States Patent 6,188,926 (to Vock) discloses a control unit for adjusting a cardiac pacing rate of a pacing unit to an interference backup rate when heart activity cannot be sensed due to EMI.

Although, conventional medical devices provide some means for protection against electromagnetic interference, these conventional devices require much circuitry and fail to provide fail-safe protection against radiation produced by magnetic-resonance imaging procedures. Moreover, the conventional devices fail to address the possible damage that can be done at the tissue interface due to RF-induced heating, and they fail to address the unwanted heart stimulation that may result from RF-induced electrical currents.

Thus, it is desirable to provide protection against electromagnetic interference, without requiring much circuitry and to provide fail-safe protection against radiation produced by magnetic-resonance imaging

Figure 3 is a block diagram of one embodiment of a MRI immune cardiac assist system according to some or all of the concepts of the present invention;

Figure 4 is a block diagram of another embodiment of a MRI immune cardiac assist system according to some or all of the concepts of the present invention;

5

10

15

20

25

Figures 5 through 20 are schematics of various optical sensing devices according to some or all of the concepts of the present invention;

Figure 21 illustrates a pressure optical transducer according to some or all of the concepts of the present invention;

Figures 22 through 26 are block diagrams of various pressure optical transducers according to some or all of the concepts of the present invention;

Figure 27 is a partial view of a cardiac assist device according to some or all of the concepts of the present invention with an intermediate portion of the photonic catheter thereof removed for illustrative clarity;

Figure 28 is an enlarged partial perspective view of components located at the distal end of the photonic catheter Figure 27;

Figure 29 is a detailed partial schematic view showing one construction of an electro-optical transducer according to some or all of the concepts of the present invention;

Figure 30 illustrates a block diagram of a cardiac assist system;

Figure 31 is a graph depicting a typical pulse sequence used in pacing a human heart, over an interval equivalent to a nominal 1 Hz human heartbeat;

Figure 32 is a similar graph depicting the pacing pulse as shown in Figure 31, but with a much finer time scale;



## PATENT APPLICATION NUMBER: 10/077,972 ATTORNEY Docket Number: BTI-6

## ATTACHMENT A MARKED-UP COPY OF AMENDED CLAIM 1

1. (Amended) A cardiac assist system, comprising:

a primary device housing; and

said primary device housing having a control circuit therein;

a lead system to transmit and receive signals between a desired anatomical cardiac tissue region and said primary device housing;

said lead system including a sensing and stimulation system at <u>a lead</u> [an epicardial-lead] interface with the desired anatomical cardiac tissue region;

said sensing and stimulation system including optical sensing components to detect physiological signals from the desired anatomical cardiac tissue region and electrical sensing components to detect physiological signals from the desired anatomical cardiac tissue region.

